PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Martin T. Gerber; John M. Swoyer	Confirmation No.	1410
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Group Art Unit:	3762		
Docket No.:	1023-277US01		
Title:	IMPLANTABLE STIMULATION LEAD WITH FIXATION MECHANISM		

APPEAL BRIEF

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Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

This is an appeal from the Office Action mailed on April 5, 2007 finally rejecting claims 1-63. The Notice of Appeal was filed on August 6, 2007. The period of response for filing this Brief runs through October 6, 2007.

Please charge Deposit Account No. 50-1778 in the amount of $510.00 to cover the required fee for filing this Brief. Please charge any additional fees that may be required or credit any overpayment to Deposit Account No. 50-1778.

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REAL PARTY OF INTEREST

The Real Party of Interest is Medtronic, Inc. of Minneapolis, Minnesota.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences for the above-referenced patent application.

STATUS OF CLAIMS

Claims 1-63 are pending and are the subject of this Appeal. The pending claims 1-63 are set forth in Appendix A.

Claims 1-3, 7-14, 16-24, 28-35, 37-55, and 58-63 stand rejected under 35 U.S.C. § 102(b) as being unpatentable over U.S. Patent No. 5,531,779 to Dahl et al. (hereinafter "Dahl").

Claims 15 and 36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dahl.

Claims 4-6, 25-27, 56, and 57 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dahl in view of U.S. Patent No. 6,077,298 to Tu et al. (hereinafter "Tu").

STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final Office Action mailed April 5, 2007, from which this Appeal has been made.

SUMMARY OF CLAIMED SUBJECT MATTER

In general, the invention relates to implantable neurostimulation leads and methods for implanting the neurostimulation leads, where the leads include a fixation mechanism that helps prevent lead migration.[1] The fixation mechanism provides a less invasive technique for fixating the leads as compared to sutures or other surgical procedures.

[1] *See, e.g., Appellant's originally-filed disclosure at p. 3, ll. 20-23.*

Independent claim 1 is directed to a neurostimulation lead comprising a lead body[2] having a proximal end and a distal end, a plurality of stimulation electrodes[3] disposed adjacent the distal end of the lead body, and a fixation mechanism[4] mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, where the position is axially displaced from the plurality of stimulation electrodes[5]. The fixation mechanism includes one or more wire-like elements[6] that are expandable to fix the lead body at a tissue target site. The position of the fixation mechanism, i.e., axially displaced from the plurality of stimulation electrodes and between one of the electrodes and the proximal end of the lead body, enables the fixation mechanism to substantially fix the electrodes in place relative to a target stimulation site.[7]

Independent claim 22 is directed to a neurostimulation system comprising an implantable neurostimulation pulse generator[8], a lead body[9] having a proximal end and a distal end, a plurality of stimulation electrodes[10] disposed adjacent the distal end of the lead body, an electrical conductor to electrically couple the implantable neurostimulation energy generator to a number of the electrodes[11], and a fixation mechanism[12] mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, where the position is axially displaced from the plurality of stimulation electrodes[13]. The fixation mechanism includes one or more wire-like elements[14] that are expandable to fix the lead body at a tissue target site.

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[2] *See, e.g., id. at FIG. 3 and p. 8, l. 13.*
[3] *See, e.g., id. at p. 7, ll. 27-28, p. 9, ll. 12-13, p. 11, ll. 5-6, and electrodes 24 in FIGS. 3-6C.*
[4] *See, e.g., id. at p. 10, ll. 18-19, fixation mechanism 34 in FIG. 3, fixation mechanism 43 in FIGS. 4A-4B, fixation mechanism 43' in FIGS. 5A-5B, and fixation mechanism 63 in FIGS. 6A-6C.*
[5] *See, e.g., id. at FIGS. 4A-6C and the Amendment to the Specification in the Amendment dated January 18, 2007.*
[6] *See, e.g., Appellant's originally-filed disclosure at p. 11, ll. 6-7, and wire-like elements 42 in FIGS. 4A-4B, wire-like elements 52 in FIGS. 5A-5B, and wire-like elements 62 in FIGS. 6A-6C.*
[7] *See, e.g., id. at p. 10, ll. 20-22.*
[8] *See, e.g., id. at p. 7, ll. 23 and p. 9, ll. 16-19.*
[9] *See, e.g., Appellant's disclosure at FIG. 3 and p. 8, l. 13.*
[10] *See, e.g., id. at p. 7, ll. 27-28, p. 9, ll. 12-13, p. 11, ll. 5-6, and electrodes 24 in FIGS. 3-6C.*
[11] *See, e.g., id. at p. 8, ll. 3-5 and p. 9, ll. 15-16.*
[12] *See, e.g., id. at p. 10, ll. 18-19, fixation mechanism 34 in FIG. 3, fixation mechanism 43 in FIGS. 4A-4B, fixation mechanism 43' in FIGS. 5A-5B, and fixation mechanism 63 in FIGS. 6A-6C.*
[13] *See, e.g., id. at FIGS. 4A-6C and the Amendment to the Specification in the Amendment dated January 18, 2007.*
[14] *See, e.g., Appellant's originally-filed disclosure at p. 11, ll. 6-7, and wire-like elements 42 in FIGS. 4A-4B, wire-like elements 52 in FIGS. 5A-5B, and wire-like elements 62 in FIGS. 6A-6C.*

Independent claim 42 is directed to a method comprising inserting a lead introducer into a patient[15] and inserting a lead into the patient via the introducer[16]. The lead includes a lead body[17] having a proximal end and a distal end, a plurality of stimulation electrodes[18] disposed on the lead body, and a fixation mechanism[19] mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the position being axially displaced from the plurality of stimulation electrodes[20]. The fixation mechanism includes one or more wire-like elements[21] that are expandable to fix the lead body at a tissue target site. In accordance with claim 42, the method further includes removing a restraint mechanism on the fixation mechanism[22], thereby permitting the wire-like elements to expand.

Independent claim 53 is directed to a stimulation lead comprising a lead body[23] having a proximal end and a distal end, a plurality of stimulation electrodes[24] disposed on the lead body, and means for fixing[25] the lead body relative to tissue proximate a target stimulation site. The fixing means includes wire-like elements[26] that are expandable to fix the lead body at a tissue target site. The fixing means is mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, and the position is axially displaced from the plurality of stimulation electrodes[27].

Dependent claim 58 depends from independent claim 53 and recites a means for restraining the wire-like elements again expansion[28], where the wire-like elements expand upon removal of at least part of the restraining means.

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[15] *See, e.g., id. at FIG. 7 and p. 16, ll. 25-27.*
[16] *See, e.g., id. at FIG. 7 and p. 17, ll. 3-5.*
[17] *See, e.g., id. at FIG. 3 and p. 8, l. 13.*
[18] *See, e.g., id. at p. 7, ll. 27-28, p. 9, ll. 12-13, p. 11, ll. 5-6, and electrodes 24 in FIGS. 3-6C.*
[19] *See, e.g., id. at p. 10, ll. 18-19, fixation mechanism 34 in FIG. 3, fixation mechanism 43 in FIGS. 4A-4B, fixation mechanism 43' in FIGS. 5A-5B, and fixation mechanism 63 in FIGS. 6A-6C.*
[20] *See, e.g., id. at FIGS. 4A-6C and the Amendment to the Specification in the Amendment dated January 18, 2007.*
[21] *See, e.g., Appellant's originally-filed disclosure at p. 11, ll. 6-7, and wire-like elements 42 in FIGS. 4A-4B, wire-like elements 52 in FIGS. 5A-5B, and wire-like elements 62 in FIGS. 6A-6C.*
[22] *See, e.g., id. at FIG. 7 and p. 17, ll. 20-22.*
[23] *See, e.g., id. at FIG. 3 and p. 8, l. 13.*
[24] *See, e.g., id. at p. 7, ll. 27-28, p. 9, ll. 12-13, p. 11, ll. 5-6, and electrodes 24 in FIGS. 3-6C.*
[25] *See, e.g., id. at p. 10, ll. 18-19, p. 7, ll. 8-10, p. 10, l. 22 to p. 11, ll. 2, p. 11, ll. 7-14, p. 13, l. 26 to p. 14, l. 2, p. 14, ll. 19-24, fixation mechanism 34 in FIG. 3, fixation mechanism 43 in FIGS. 4A-4B, fixation mechanism 43' in FIGS. 5A-5B, and fixation mechanism 63 in FIGS. 6A-6C.*
[26] *See, e.g., id. at p. 11, ll. 6-7, and wire-like elements 42 in FIGS. 4A-4B, wire-like elements 52 in FIGS. 5A-5B, and wire-like elements 62 in FIGS. 6A-6C.*
[27] *See, e.g., id. at FIGS. 4A-6C and the Amendment to the Specification in the Amendment dated January 18, 2007.*
[28] *See, e.g., id. at p. 4, ll. 6-13, p. 12, ll. 20-26, and p. 14, ll. 25-26, and stylet 66.*

Dependent claims 3, 24, and 55 depend from independent claims 1, 22, and 53, respectively, and each recite a fixation mechanism that includes wire-like elements each having a proximal joint[29] where a proximal end of the respective wire-like element meets the lead body and a distal joint[30] where a distal end of the respective wire-like element meets the lead body, and where the distal joint is weaker than the proximal joint.[31] After a lead has been implanted within a patient for an amount of time, fibrous ingrowth may develop around the lead.[32] The weaker distal joint provides a feature that helps facilitate explantation of a lead, for example, by reducing resistance attributable to the fibrous ingrowth.[33] For example, during explantation of the lead, the weaker distal joint may break under sufficient force, thereby allowing the wire-like elements of the fixation mechanism to be withdrawn around the fibrous ingrowth.[34]

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellant submits the following grounds of rejection to be reviewed on Appeal:

1. The rejection of claims 1-3, 7-14, 16-24, 28-35, 37-55, and 58-63 under 35 U.S.C. § 102(b) as being unpatentable over Dahl;

2. The rejection of claims 15 and 36 under 35 U.S.C. § 103(a) as being unpatentable in view of Dahl; and

3. The rejection of claims 4-6, 25-27, 56, and 57 under 35 U.S.C. § 103(a) as being unpatentable over Dahl in view of Tu.

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[29] *See, e.g., id. at FIG. 6C and p. 16, ll. 4-6.*
[30] *See, e.g., id.*
[31] *See, e.g., id. at p. 16, ll. 6-12.*
[32] *See, e.g., id. at p. 15, l. 28 – p. 16, l. 2 and FIGS. 6B-6C (fibrous ingrown 69).*
[33] *See, e.g., id.*
[34] *See, e.g., id. at FIG. 6C.*

ARGUMENT

Appellant respectfully traverses the current rejections advanced by the Examiner, and requests reversal of such rejections by the Board of Patent Appeals based on the arguments below.

First Ground of Rejection Under Appeal

Claims 1-3, 7-14, 16-24, 28-35, 37-55, and 58-63 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Dahl. Appellant respectfully submits that the rejection of claims 1-3, 7-14, 16-24, 28-35, 37-55, and 58-63 was in error and should be reversed. In order to support an anticipation rejection under 35 U.S.C. § 102(b), it is well established that a prior art reference must disclose each and every element of a claim.[35] If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. 102(b) is improper. [36] Dahl fails to disclose each and every element of Appellant's claims, and accordingly, the Examiner's rejection of Appellant's independent claims was improper and should be reversed.

Independent Claims 1, 22, 42, and 53

Independent claims 1 and 22 each recite a lead that comprises a lead body, a plurality of stimulation electrodes, and a fixation mechanism including one or more wire-like elements that are expandable to fix a lead body at a target tissue site, where the fixation mechanism is mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the position also being axially displaced from the plurality of stimulation electrodes. Independent claim 42 relates to a method that includes inserting such a lead. Independent claim 53 recites a lead a lead body, a plurality of stimulation electrodes, and a means for fixing the lead body to tissue proximate a target stimulation site, where the fixing means is mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the position also being axially displaced from the plurality of stimulation electrodes.

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[35] *See Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986) ("it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention").*

[36] *Id.; see also Lewmar Marine, Inc. v. Barient, Inc. 827 F.2d 744, 3 USPQ.2d 1766 (Fed. Cir. 1987); In re Bond, 910 F.2d 831, 15 USPQ.2d 1566 (CAFC 1990); C.R. Bard, Inc. v. MP Systems, Inc., 157 F.3d 1340, 48 USPQ.2d 1225 (Fed. Cir. 1998); Oney v. Ratliff, 182 F.3d 893, 51 USPQ.2d 1697 (Fed. Cir. 1999); Apple Computer, Inc. v. Articulate Systems, Inc., 234 F.3d 14, 57 USPQ.2d 1057 (Fed. Cir. 2000).*

Dahl fails to disclose or suggest each and every element of independent claims 1, 22, 42, and 53. For example, Dahl fails to disclose or suggest a lead comprising a fixation mechanism mounted to a lead body at a position between one of a plurality of stimulation electrodes and a proximal end of the lead body, the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site, where the position is axially displaced from the plurality of stimulation electrodes, as recited by claims 1 and 22.

As FIG. 4B (copied below) of Appellant's disclosure illustrates, the fixation mechanism 43 and plurality of stimulation electrodes 24 are positioned at different locations on the lead body 41 of lead 40, such that the fixation mechanism 43 is axially displaced from the plurality of stimulation electrodes 24.

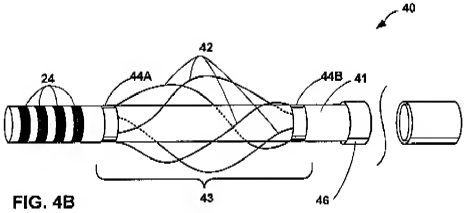

FIG. 4B

In support of the rejection of Appellant's claim 1, the Office Action characterized ring electrodes 46 and 48 in Dahl as the plurality of electrodes and the wire filaments 50 as a fixation mechanism. FIG. 6 of Dahl, which illustrates the ring electrodes 46 and 48 and wire filaments 50, is copied below.

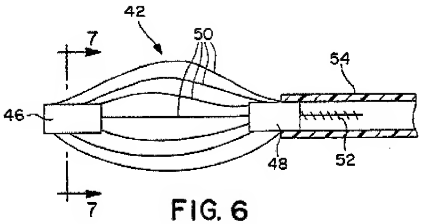

FIG. 6

As explicitly disclosed by Dahl, the ring electrodes 46 and 48 and wire filaments 50 define a single electrode structure, and, therefore, cannot be a plurality of stimulation electrodes and fixation mechanism axially displaced from the plurality of stimulation electrodes recited in Appellant's independent claims 1 and 22. In particular, Dahl describes a lead that includes an electrode structure 42 (shown in FIG. 6), where the electrode structure 42 includes a pair of spaced ring electrodes 46 and 48 interconnected by a circumferential array of wire filaments 50.[37] The ring electrode 48 is connected to a single conductor 52 in order to connect the entire electrode structure 42 to a pulse generator 10.[38] Thus, the ring electrodes 46 and 48 and the wire-like filaments 50 are electrically connected and define a single electrode of the lead.

Each and every claim term must be given meaning, and the claimed invention as a whole must be considered.[39] Appellant's claims 1 and 22 clearly recite a plurality of stimulation electrodes in addition to a fixation mechanism that is axially displaced from the plurality of stimulation electrodes. Dahl does not disclose a lead that includes both a plurality of stimulation electrodes and a fixation mechanism.

Furthermore, Dahl does not disclose a fixation mechanism that is axially displaced from a plurality of electrodes, as required by Appellant's independent claims. Dahl teaches a single electrode structure that includes wire filaments 50, where each and every element of the electrode structure is electrically connected to define a single electrode assembly sharing a polarity. As a result of the shared polarity and the interconnection of each of the elements of the electrode structure taught by Dahl, the wire filaments 50 cannot be a fixation mechanism that is

[37] *Dahl at col. 4, l. 61 to col. 5, l. 8.*
[38] *Id. at col. 5, ll. 19-26.*
[39] *MPEP § 2141.02.*

positioned at a location of the lead body that is axially displaced from a plurality of stimulation electrodes. Rather, the wire filaments 50 taught by Dahl are an integral part of a single stimulation electrode formed by several co-located and electrically interconnected elements.

FIG. 2 of Dahl illustrates two stent electrode structures 40 and 42. Even if one stent electrode structure is considered to be a stimulation electrode and the other stent electrode structure is considered to be a fixation mechanism, Dahl still does not teach a plurality of electrodes in addition to a fixation mechanism nor a fixation mechanism that is axially displaced from the electrodes. The lead 44 shown in FIG. 2 only includes two electrode structures 40 and 42, and Dahl does not contemplate the addition of other electrodes to lead 44. Furthermore, because the electrode structures 40 and 42 are the electrodes of the lead 44, FIG. 2 of Dahl does not illustrate a lead including a fixation mechanism that includes one or more wire-like elements, where the fixation mechanism is axially displaced from the plurality of stimulation electrodes of the lead.

For similar reasons, Dahl also fails to disclose or suggest a lead that includes a plurality of stimulation electrodes and means for fixing the lead body, where the fixing means is axially displaced from t he plurality of stimulation electrodes, as recited by Appellant's claim 53. In addition, Dahl fails to disclose or suggest a method that includes inserting a lead into a patient, where the lead includes a plurality of stimulation electrodes and a fixation mechanism axially displaced from the plurality of stimulation electrodes, as recited by Appellant's claim 42.

For at least these reasons, Dahl fails to disclose or suggest each and every element of independent claims 1, 22, 42, and 53, and the rejection of claims 1, 22, 42, and 53 should be reversed.

Dependent Claims

Claims 2-3, 7-14, 16-21, 60, and 61 depend from claim 1, claims 23, 24, 28-35, 37-41, 62, and 63 depend from claim 22, claims 43-52 depend from claim 42, and claims 53-55, 58, and 59 depend from claim 52. As established above, independent claims 1, 22, 43, and 52 are patentable over the Dahl, and as a result, all claims depending therefrom are also patentable over Dahl. Dahl also fails to anticipate the further requirements recited in dependent claims 2, 3, 7-14, 16-21, 23, 24, 28-35, 37-41, 43-55, and 58-63. The prior art of record fails to teach each and

every element of the dependent claims, and the rejection should be reversed. Appellant addresses some of the dependent claims below for purposes of illustration.

Claims 2, 23, 52, and 54

Claims 2, 23, 52, and 54 each specify that the wire-like elements of the fixation mechanism or means for fixing a lead body includes an elastic material. While Dahl discloses wire filaments 24, 50 that may be radially resiliently compressed[40], Dahl only contemplates wire filaments 24, 50 that are constructed of MP35N (a metal alloy) coated with platinum.[41] Dahl does not teach wire-like elements that include an elastic material.

In addition, the rejection of claims 2, 23, 53, and 54 should be reversed because the Examiner has failed to meet the burden of illustrating how Dahl anticipates claims 2, 23, 52, and 54. As provided in 37 C.F.R. 1.104(c) (2), the Examiner must designate the particular part of a reference as nearly as practicable. However, with respect to claims 2, 23, 52, 54, as well as many of the other dependent claims, the Examiner has failed to do so. To the extent the final Office Action mailed on April 5, 2007 provides support for the assertion that Dahl discloses each and every element of claims 1-3, 7-14, 16-24, 28-35, 37-55, and 58-63, the Office Action states:

> Dahl et al disclose a first ring electrode 46 and a second ring electrode 48 that retain wire-like elements 50 that are expandable to fix the lead body at a tissue target site. The lead disclosed in Dahl et al is capable of being used as a neurostimulation lead and as such meets the claim limitations.

The Examiner does not explain what parts of Dahl disclose a fixation mechanism that includes wire-like elements including an elastic material. Accordingly, the rejection of claims 2, 23, 52, and 54 was improper and should be reversed.

Claims 3, 24, 45, and 55

Claims 3, 24, and 55 each recite a fixation mechanism or a means for fixing a lead body, where the fixation mechanism or fixing means includes wire-like elements each having a proximal joint where a proximal end of the respective wire-like element meets the lead body and a distal joint where a distal end of the respective wire-like element meets the lead body, and where the distal joint is weaker than the proximal joint. An example of wire-like elements

[40] *Dahl at col. 4, ll. 1-7 and col. 5, ll. 17-19.*
[41] *Id. at col. 4, l. 3 and col. 5, l. 8.*

including a weaker distal joint is shown in FIGS. 6A-6C of Appellant's originally filed disclosure. FIGS. 6B and 6C are copied below.

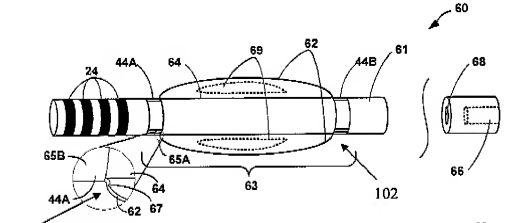

FIG. 6B

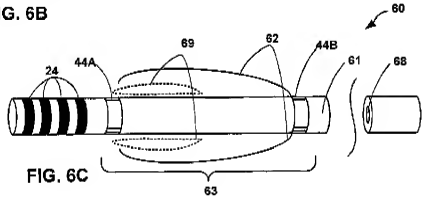

FIG. 6C

In the FIG. 6B, the wire-like elements 62 of the fixation mechanism 63 each include a distal joint (labeled as "100" in FIG. 6B above) that is weaker than a proximal joint (labeled "102" in FIG. 6B above). As provided in Appellant's originally-filed disclosure, in some embodiments, the distal joint 100 of wire-like element 62 may be intentionally thinned to create a breakpoint that causes wire-like element 62 to break under sufficient force.[42] Examples provided in Appellant's disclosure include engineering the distal joint 100 to be weaker than the proximal joint 102 by perforating, scoring, thinning, or otherwise working the distal joint to break away under force generated by withdrawal of lead 60 from a target site.[43] A weaker distal joint 100 may be useful when withdrawing a lead from fibrous ingrowth 69 (shown in FIG. 6C).

A weaker distal joint provides a feature that helps facilitate explantation of a lead, for

[42] *Appellant's originally-filed disclosure at paragraph [0070].*
[43] *Id. at paragraph [0071].*

example, by reducing resistance attributable to the fibrous ingrowth.[44] By promoting breakage of the distal joint during explantation of the lead, the wire-like elements of the fixation mechanism may be withdrawn around the fibrous ingrowth.[45] Reducing resistance during lead withdrawal that is attributable to fibrous ingrowth may help minimize damage to tissue surrounding the lead during lead explantation, as well as minimize the amount of force necessary to withdraw the lead from a patient.

As an initial matter, Appellant notes that the Examiner has also failed to meet the burden of illustrating how the cited references teach or suggest the elements recited in claims 3, 24, 45, and 55. During the prosecution of the Appellant's case, the Examiner has failed to provide any support for the conclusion that claims 3, 24, 45, and 55 are anticipated by Dahl. For example, the Examiner does not cite to disclosure within Dahl that demonstrates Dahl discloses wire-like elements having a proximal joint and a distal joint that is weaker than the proximal joint.

Dahl fails to disclose or suggest wire-like elements having a proximal joint and a distal joint that is weaker than the proximal joint, as required by claims 3, 24, and 55. Dahl states that the wire filaments 50 of its electrode structure 42 are welded to the ring electrodes 46 and 48.[46] However, Dahl makes no mention of joint strength and lacks any disclosure that would have suggested the requirements of claims 3, 24, and 55. Dahl completely lacks any disclosure relating to wire-like element joints, much less any wire-like element configuration that aids the withdrawal of the lead from a patient. Accordingly, the Examiner lacks any basis for finding that claims 3, 24, and 55 are anticipated by Dahl.

With respect to claim 45, Dahl fails to disclose or suggest detaching a distal end of each wire-like element and withdrawing the lead from the target site. Dahl does not disclose removing a lead from a target site and certainly does not disclose or suggest detaching a distal end of each wire-like element. The Examiner fails to point to any suggestion of such a feature in Dahl, and seemed to overlook this requirement. For at least these reasons, Dahl fails to disclose or suggest the requirements of claim 45.

Given the fact that Dahl clearly fails to provide any disclosure that discloses or even suggests the limitations of claims 3, 24, 45, and 55, and the fact that the Examiner has

[44] *See, e.g., id.*
[45] *See, e.g., id.* at FIG. 6C.
[46] *Dahl at col. 5, ll. 8-10.*

completely failed to provide support for the rejection of claims 3, 24, 45, and 55, the rejection of claims 3, 24, 45, and 55 was improper.

Claims 10 and 31

Claims 10 and 31 each specify that a restraint mechanism restrains the wire-like elements of the fixation mechanism against expansion, where the restraint mechanism includes a stylet that is accommodated by an inner lumen of the lead. Claim 43 recites a method that includes removing a restraint by withdrawing at least part of a stylet from a lumen of the lead, thereby releasing a fixation mechanism to expand. The Examiner failed to show how Dahl discloses the elements of claim 10, 31, and 43, and accordingly, did not meet the burden of showing anticipation of each and every element of claims 10, 31, and 43.

Dahl does not disclose or suggest the elements of claims 10, 31 or 43. While Dahl describes using a stylet wire to position a distal end of an electrode at a location within a vessel,[47] Dahl does not disclose or suggest using a stylet as a restraint mechanism. The only restraint mechanism contemplated by Dahl includes a constraining catheter 34.[48] As shown in FIG. 3 (copied below) of Dahl, the constraining catheter 34 compresses the wires 24 from outside of the stent, and is not accommodated by an inner lumen of the lead. Accordingly, claims 10, 31, and 43 are patentable over Dahl.

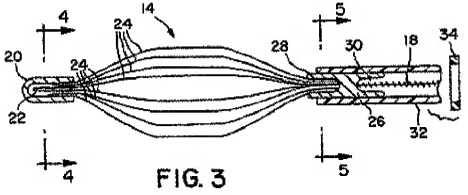

FIG. 3

[47] *Id.* at col. 4, ll. 49-54.
[48] *Id.* at col. 4, ll. 30-33.

Claims 11 and 32

Claims 11 and 32 each recite a lead including a lead body, where at least a portion of the lead body is elastic, causing a diameter of the lead body to decrease when the lead body portion is stretched. Claim 62, which depends from claim 32, recites a stylet that provides an axial force that stretches the elastic portion of the lead body to restrain the wire-like elements against expansion, and claim 63, which depends from claim 62, specifies that the elastic portion of the lead body decreases in length upon removal of the stylet. Dahl, in contrast, describes an outer catheter, and makes no mention of an inner stylet that provides an axial force to stretch a lead body.

Again, the Examiner has failed to meet the burden of showing how Dahl anticipates claims 11, 32, 62, and 63. The Examiner has provided absolutely no explanation of how Dahl discloses a lead body including an elastic portion or a stylet that provides an axial force that stretches the elastic portion. The rejection of claims 11, 32, 62, and 63 is, therefore, improper and should be reversed.

Dahl describes a stent electrode structure (i.e., a plurality of conductive wires[49]) that has a larger diameter and reduced length in its relaxed state than in its constrained state.[50] According to Dahl, the diameter of the stent electrode structure may be reduced by increasing the length of the stent electrode.[51] However, Dahl does not disclose or suggest a lead body with an elastic portion that causes a diameter of the lead body portion to decrease when the lead body portion is stretched. While Dahl refers to a "stent" that increases in length, in the context of the Dahl disclosure, Dahl appears to be shortening the term "stent electrode structure" to "stent."[52] For at least these reasons, Dahl fails to meet the requirements of claims 11, 32, 62, and 63.

Claims 16-19, 37-40, and 48-51

Claims 16-19, 37-40, and 48-51 each recite a fixation mechanism that is sized to be expandable to a diameter in a particular range. For example, claims 16, 37, and 40 each recite a fixation mechanism that is sized to be expandable to a diameter in a range of about 2 millimeters

[49] *Id.* at col. 2, ll. 62-65.
[50] *Id.* at col. 2, ll. 42-56.
[51] *Id.*
[52] *See, e.g., id.* at col. 2, ll. 43-45 ("It is understood . . . that a stent electrode structure is an electrically conducting structure . . . It is contemplated that the stent can be compressed." (emphasis added)).

(mm) to about 10 mm. As provided in Appellant's disclosure, a range of about 2 mm to about 10 mm may be useful for a tissue site within a sacral foramen.[53] As another example, a range of about 6 mm to about 15 mm, as recited in claims 18, 39, and 51, is useful for a tissue site in the epidural region.[54]

Dahl fails to anticipate claims 16-19, 37-40, and 48-51, and the Examiner has failed to meet the burden of demonstrating how Dahl discloses each and every element of claims 16-19, 37-40, and 48-51. Dahl only describes and contemplates electrodes that may be positioned in one of the great veins or arteries of the heart for treatment of cardiac arrhythmias. The electrodes are sized such that, "the diameter of the structure substantially corresponds with the diameter of the [interior vena cava]."[55] Dahl does not specify the diameter of its electrode wires and does not contemplate using the electrodes for other applications. In particular, Dahl does not disclose or suggest a lead that is configured for sacral, pudendal, or spinal cord applications.

For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Appellant's claims 1-3, 7-14, 16-24, 28-35, 37-55, and 58-63 under 35 U.S.C. § 102(b). Reversal of this rejection is requested.

Second Ground of Rejection Under Appeal

Claims 15 and 36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dahl. However, Dahl fails to teach or suggest the elements of claims 15 and 16, which recite a lead that includes at least four electrodes. In support of the rejection of claims 15 and 36, the Examiner stated that it would have been obvious to double the number of electrodes disclosed in Dahl because it is well known to duplicate parts.[56] The Examiner's reasoning, however, does not provide any motivation for modifying the Dahl lead to include more than two electrodes. In addition, the Examiner's reasoning fails to consider the lack of a reasonable expectation of success that modifying the Dahl device to include more than two electrodes would work for the intended purpose.

The Dahl electrode structures, which the Examiner characterized as a fixation mechanism, are configured to be introduced into a vein, such that the electrode structure contacts

[53] *Appellant's originally-filed disclosure at paragraph [0055].*
[54] *Id.*
[55] *Dahl at col. 3, ll. 45-52.*
[56] *Final Office Action mailed April 5, 2007 at p. 3.*

the inner wall of the vein in order to supply electrical shock therapy to the heart.[57] According to Dahl, the "nature of the stent structure still allows for substantially unimpeded blood flow through the [inferior vena cava]."[58]

The Examiner has provided no basis for asserting that modifying the Dahl device to include at least four electrode structures that contact the inner wall of a vein will reasonably continue to allow for the substantially unimpeded blood flow. In addition, including additional electrodes, such as ring electrodes, on the catheter at a position axially displaced from the fixation mechanism would contradict the electrical stimulation technique taught by Dahl because the additional electrodes would not contact the vessel wall. Accordingly, it would not have been obvious to one skilled in the art to modify Dahl to include a four or more stimulation electrodes axially displaced from the fixation mechanism.

In FIG. 2 and the description thereof, Dahl discloses two stent electrode structures, one positioned in the superior vena cava and the other at "the same level of the [right ventricle] apex," to provide a more comprehensive electric field as compared to a single electrode extending from above the plane of the top of the atrium to below the plane of the right ventricle apex.[59] Even if one stent electrode structure is considered to be a stimulation electrode and the other stent electrode structure is considered to be a fixation mechanism, FIG. 2 of Dahl still does not teach or suggest at least four electrodes in addition to a fixation mechanism.

It is unclear how the Dahl apparatus would deliver stimulation via a plurality of electrodes. The positions of each of the two stent electrode structures disclosed by Dahl suggest that stimulation energy provided by the two stent electrodes traverses the heart from the superior vena cava to the right ventricle apex. For example, the electrode positioned in the superior vena cava may act as an anode and the electrode positioned at the plane of the right ventricle apex may act as a cathode, allowing the electrical stimulation current to flow along the heart's natural current path. Dahl does not teach or suggest how this same electrical stimulation current path would be achieved via more than two electrodes. As Appellant's disclosure recognizes, a plurality of stimulation electrodes enables electrical pulses to be delivered to a patient via

[57] *Dahl at col. 2, ll. 45-53 and col. 3, ll. 43-52.*
[58] *Id. at col. 3, ll. 51-52.*
[59] *Id. at col. 4, ll. 57-60 and col. 5, ll. 26-34.*

selected subsets of electrodes, which may have selected polarities.[60] The apparatus taught by Dahl, on the other hand, does not teach a plurality of electrodes, much less an apparatus that permits particular electrode combinations to be selected.

Dahl is related to an intravenous lead that includes an intravascular electrode structure that applies electrical therapy to a vein of the heart.[61] On the other hand, Appellant's claims 15 and 36 relate to a neurostimulation lead that includes at least four electrodes. The four electrodes enable electrical stimulation to be provided via more electrode combinations than a lead that includes two electrodes. A neurostimulation lead that permits neurostimulation pulses to be delivered via selected subsets of electrodes with selected polarities may enable the neurostimulation therapy to treat different symptoms and/or provide a combined therapeutic effect by providing stimulation to more than one target stimulation site.[62]

The intravenous lead taught by Dahl that includes two electrodes, on the other hand, cannot provide deliver electrical pulses via different subsets of electrodes. Dahl does not contemplate a therapy system that includes selecting different subsets of electrodes of a lead, and, accordingly, it would not have been obvious to modify Dahl to double the number electrodes, as the Examiner asserted.[63] Absent some reason to include more than four electrodes, one skilled in the art would not have been motivated to "duplicate parts" of the Dahl intravenous lead for providing stimulation to a patient's heart.

For at least these reasons Dahl fails to disclose or suggest a lead including a four or more electrodes in addition to a fixation mechanism, as recited by claims 15 and 36.

Third Ground of Rejection Under Appeal

Claims 4-6, 25-27, 56, and 57 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dahl in view of Tu. Initially, Appellant notes that Tu provides no teaching that would have overcome the deficiencies of Dahl with respect to the requirements Appellant's independent claims discussed above. Moreover, Dahl in view of Tu fails to disclose or teach each and every element of claims 4-6, 25-27, 56, and 57.

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[60] *Appellant's originally-filed disclosure at paragraphs [0043] and [0044].*
[61] *Dahl at col. 2, ll. 3-10.*
[62] *Appellant's originally-filed disclosure at paragraphs [0044] and [0045].*
[63] *Final Office Action dated April 5, 2007 at p. 3.*

In support of the rejection of claims 4-6, 25-27, 56, and 57, the Examiner stated that it would have been obvious to modify the wire-like elements disclosed in Dahl to include the shape-memory Nitinol material disclosed in Tu, because the wire-like elements of Dahl provide an equivalent function as the stent disclosed by Tu.[64]

Appellant disagrees with this motivation for modifying the Dahl electrode structure to include the Nitinol tubular stent. Tu describes a stent that includes Nitinol as one of the construction materials in order to allow the stent to be collapsed into its unexpanded state to aid in retraction of the stent from a vessel of a patient.[65] Dahl does not contemplate removal of a catheter and certainly does not disclose or suggest retracting the electrode structures to aid in the removal of the catheter. Thus, it is unclear why one of ordinary skill in the art would have looked to Tu to modify the Dahl device. Furthermore, even if Dahl were modified in view of Tu, the resulting device would not result in the claimed lead of Appellant's claims 4-6, 25-27, 56, and 57 because Tu does not contemplate Nitinol wire-like elements, but Nitinol coil wires secured to another coil wire to define a tubular stent.[66]

For at least these reasons, the Examiner has failed to establish a prima facie case for obviousness of Appellant's claims 4-6, 15, 25-27, 36, 56, and 57 under 35 U.S.C. § 103(a). Reversal of this rejection is requested.

[64] *Id. at p. 3.*
[65] *Tu at col. 2, ll. 45-54.*
[66] *Id. at col. 6, ll. 38-62.*

CONCLUSION

The Examiner has failed to meet the burden of establishing a prima facie case of anticipation or obviousness with respect to claims 1-63. In view of Appellant's arguments, the final rejection of claims 1-63 is improper and should be reversed, and all of the pending claims should be allowed. Appellant respectfully requests separate review by the Board for each of the grounds or rejection addressed above under separate headings.

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By: Jessica H. Kwak

SHUMAKER & SIEFFERT, P.A.
1625 Radio Drive, Suite 300
Woodbury, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

Name: Jessica H. Kwak
Reg. No.: 58,975

APPENDIX A

THE CLAIMS ON APPEAL

Claim 1 (Previously Presented): A neurostimulation lead comprising:

a lead body having a proximal end and a distal end;

a plurality of stimulation electrodes disposed adjacent the distal end of the lead body; and

a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site, wherein the position is axially displaced from the plurality of stimulation electrodes.

Claim 2 (Original): The neurostimulation lead of claim 1, wherein each of the wire-like elements includes an elastic material.

Claim 3 (Original): The neurostimulation lead of claim 1, each of the wire-like elements having a proximal joint where the proximal end of the wire-like element meets the lead body, and a distal joint where the distal end of the wire-like element meets the lead body, wherein the distal joint is weaker than the proximal joint.

Claim 4 (Previously Presented): The neurostimulation lead of claim 1, wherein each of the wire-like elements includes a shape memory alloy.

Claim 5 (Original): The neurostimulation lead of claim 1, wherein each of the wire-like elements includes a super-elastic material.

Claim 6 (Original): The neurostimulation lead of claim 4, wherein the shape memory alloy includes Nitinol.

Claim 7 (Original): The neurostimulation lead of claim 1, further comprising an inner lumen to accommodate a stylet.

Claim 8 (Original): The neurostimulation lead of claim 1, further comprising a restraint mechanism to restrain the wire-like elements against expansion, wherein the wire-like elements expand upon removal of at least part of the restraint mechanism.

Claim 9 (Original): The neurostimulation lead of claim 8, wherein the restraint mechanism includes a lead introducer, the lead introducer defining a lead introducer lumen sized to accommodate the stimulation lead body.

Claim 10 (Original): The neurostimulation lead of claim 8, wherein the restraint mechanism includes a stylet, the stylet accommodated by an inner lumen of the neurostimulation lead.

Claim 11 (Original): The neurostimulation lead of claim 1, wherein at least a portion of the lead body is elastic, causing a diameter of the lead body portion to decrease when the lead body portion is stretched.

Claim 12 (Original): The neurostimulation lead of claim 1, wherein each of the wire-like elements is configured in a substantial helical shape.

Claim 13 (Original): The neurostimulation lead of claim 1, further comprising retainer rings mounted about the lead body to retain opposite ends of each of the wire-like elements.

Claim 14 (Original): The neurostimulation lead of claim 1, wherein one of the wire-like elements acts as an electrode for neurostimulation current.

Claim 15 (Previously Presented): The neurostimulation lead of claim 1, wherein the plurality of electrodes include at least four electrodes.

Claim 16 (Original): The neurostimulation lead of claim 1, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 2 to 10 mm.

Claim 17 (Original): The neurostimulation lead of claim 1, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 4 to 6 mm.

Claim 18 (Original): The neurostimulation lead of claim 1, wherein the of the fixation mechanism is sized to be expandable to a diameter in a range of approximately 6 to 15 mm.

Claim 19 (Original): The neurostimulation lead of claim 1, wherein the of the fixation mechanism is sized to be expandable to a diameter in a range of approximately 9 to 12 mm.

Claim 20 (Original): The neurostimulation lead of claim 1, wherein the stimulation lead includes radio-opaque material that is detectable by fluoroscopic imaging.

Claim 21 (Original): The neurostimulation lead of claim 1, wherein the lead is one of a sacral lead, a pudendal nerve lead, and a spinal cord stimulation lead.

Claim 22 (Previously Presented): A neurostimulation system comprising:

an implantable neurostimulation pulse generator;

a lead body having a proximal end and a distal end;

a plurality of stimulation electrodes disposed adjacent the distal end of the lead body;

an electrical conductor to electrically couple the implantable neurostimulation energy generator to a number of the electrodes; and

a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site, wherein the position is axially displaced from the plurality of stimulation electrodes.

Claim 23 (Original): The neurostimulation system of claim 22, wherein each of the wire-like elements includes an elastic material.

Claim 24 (Original): The neurostimulation system of claim 22, each of the wire-like elements having a proximal joint where the proximal end of the wire-like element meets the lead body, and a distal joint where the distal end of the wire-like element meets the lead body, wherein the distal joint is weaker than the proximal joint.

Claim 25 (Previously Presented): The neurostimulation system of claim 22, wherein each of the wire-like elements includes a shape memory alloy.

Claim 26 (Original): The neurostimulation system of claim 22, wherein each of the wire-like elements includes a super-elastic material.

Claim 27 (Original): The neurostimulation system of claim 25, wherein the shape memory alloy includes Nitinol.

Claim 28 (Original): The neurostimulation system of claim 22, further comprising an inner lumen to accommodate a stylet.

Claim 29 (Original): The neurostimulation system of claim 22, further comprising a restraint mechanism to restrain the wire-like elements against expansion, wherein the wire-like elements expand upon removal of at least part of the restraint mechanism.

Claim 30 (Original): The neurostimulation system of claim 29, wherein the restraint mechanism includes a lead introducer, the lead introducer defining a lead introducer lumen sized to accommodate the stimulation lead body.

Claim 31 (Original): The neurostimulation system of claim 29, wherein the restraint mechanism includes a stylet, the stylet accommodated by an inner lumen of the neurostimulation lead.

Claim 32 (Original): The neurostimulation system of claim 22, wherein at least a portion of the lead body is elastic, causing a diameter of the lead body portion to decrease when the lead body portion is stretched.

Claim 33 (Original): The neurostimulation system of claim 22, wherein each of the wire-like elements is configured in a substantial helical shape.

Claim 34 (Original): The neurostimulation system of claim 22, further comprising retainer rings mounted about the lead body to retain opposite ends of each of the wire-like elements.

Claim 35 (Original): The neurostimulation system of claim 22, wherein one of the wire-like elements acts as an electrode for neurostimulation current.

Claim 36 (Original): The neurostimulation system of claim 22, wherein the electrodes include at least four electrodes.

Claim 37 (Original): The neurostimulation lead of claim 22, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 2 to 10 mm.

Claim 38 (Original): The neurostimulation lead of claim 22, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 4 to 6 mm.

Claim 39 (Original): The neurostimulation lead of claim 22, wherein the of the fixation mechanism is sized to be expandable to a diameter in a range of approximately 6 to 15 mm.

Claim 40 (Original): The neurostimulation lead of claim 22, wherein the of the fixation mechanism is sized to be expandable to a diameter in a range of approximately 9 to 12 mm.

Claim 41 (Original): The neurostimulation system of claim 22, wherein the stimulation lead includes radio-opaque material that is detectable by fluoroscopic imaging.

Claim 42 (Previously Presented): A method comprising:

inserting a lead introducer into a patient;

inserting a lead into the patient via the introducer, wherein the lead includes a lead body having a proximal end and a distal end, a plurality of stimulation electrodes disposed on the lead body, and a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the position being axially displaced from the plurality of stimulation electrodes and the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site; and

removing a restraint mechanism on the fixation mechanism, thereby permitting the wire-like elements to expand.

Claim 43 (Original): The method of claim 42, wherein removing a restraint includes withdrawing at least part of a stylet from a lumen of the lead, thereby releasing the fixation mechanism to expand.

Claim 44 (Original): The method of claim 42, wherein removing a restraint includes withdrawing at least a portion of the lead introducer, thereby releasing the fixation mechanism to expand.

Claim 45 (Original): The method of claim 42, further comprising:
detaching a distal end of each wire-like element; and
withdrawing the lead from the target site.

Claim 46 (Original): The method of claim 42, further comprising:
restraining the expanded fixation mechanism; and
withdrawing the lead from the target site.

Claim 47 (Original): The method of claim 42, wherein the restraint mechanism includes a lead introducer, the lead introducer defining a lead introducer lumen sized to accommodate the stimulation lead body.

Claim 48 (Original): The method of claim 42, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 2 to 10 mm.

Claim 49 (Original): The method of claim 42, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 4 to 6 mm.

Claim 50 (Original): The method of claim 42, wherein the of the fixation mechanism is sized to be expandable to approximately a diameter in a range of approximately 6 to 15 mm.

Claim 51 (Original): The method of claim 42, wherein the of the fixation mechanism is sized to be expandable to approximately a diameter in a range of approximately 9 to 12 mm.

Claim 52 (Original): The method of claim 42, wherein each of the wire-like elements includes an elastic material.

Claim 53 (Previously Presented): A stimulation lead comprising:

a lead body having a proximal end and a distal end;

a plurality of stimulation electrodes disposed on the lead body; and

means for fixing the lead body relative to tissue proximate a target stimulation site, wherein the fixing means includes wire-like elements that are expandable to fix the lead body at a tissue target site, ~~and~~ wherein the fixing means is mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, and the position is axially displaced from the plurality of stimulation electrodes.

Claim 54 (Original): The lead of claim 53, wherein each of the wire-like elements includes an elastic material.

Claim 55 (Original): The lead of claim 53, each of the wire-like elements having a proximal joint where the proximal end of the wire-like element meets the lead body, and a distal joint where the distal end of the wire-like element meets the lead body, wherein the distal joint is weaker than the proximal joint.

Claim 56 (Previously Presented): The lead of claim 53, wherein each of the wire-like elements includes a shape memory alloy.

Claim 57 (Original): The lead of claim 53, wherein each of the wire-like elements includes a super-elastic material.

Claim 58 (Original): The lead of claim 53, further comprising means for restraining the wire-like elements against expansion, wherein the wire-like elements expand upon removal of at least part of the restraining means.

Claim 59 (Original): The lead of claim 53, wherein the lead is one of a sacral lead, a pudendal nerve lead, and a spinal cord stimulation lead.

Claim 60 (Previously Presented): The neurostimulation lead of claim 1, further comprising a plurality of retainer rings, wherein the retainer rings mount the wire-like elements to the lead body at proximal ends and distal ends of the wire-like elements

Claim 61 (Previously Presented): The neurostimulation lead of claim 1, wherein the fixation mechanism is spring-biased.

Claim 62 (Previously Presented): The neurostimulation system of claim 32, wherein the stylet provides an axial force that stretches the elastic portion of the lead body to restrain the wire-like elements against expansion.

Claim 63 (Previously Presented): The neurostimulation system of claim 62, wherein the elastic portion of the lead body decreases in length upon removal of the stylet.

APPENDIX B
EVIDENCE

None.

APPENDIX C
RELATED PROCEEDINGS

None.